

REMARKS

After entry of the amendment, claims 1, 3-5, 7, 10-25, 55, 57-58, 61-69, 77-80, 84, 85 and 98-114 are pending. Claims 6, 8, 9 and 52 have been canceled by the present amendment. Claims 1, 3-5, 7, 11, 12, 55, 57 and 61 have been amended.

Claim 1 has been amended to clarify the composition's concentration of aqueous-soluble divalent calcium cation. Support for this amendment can be found, for example, at page 22, lines 1-7. Additionally, claim 1, as well as claims 7, 11 and 12 have been amended to clarify that more than one irritant ingredient may be present in the composition. Support for this amendment can be found, for example, in original claim 16. Claim 1 has been further amended to clarify the presence of an ionizable anion counterpart to the claimed calcium cation. Support for this amendment can be found, for example, at page 17, lines 1-9, and is further obvious in view of the principles of chemistry.

Claims 3-5 have been amended to claim the concentration of the aqueous-soluble divalent calcium cation by weight percentage.

Claim 7 has been further amended to correct dependency from a claim that has been canceled herewith.

Claims 55 and 57 have been amended to clarify the anion species as being aqueous-ionizable. Support for this amendment can be found, for example, at page 21, lines 7-21.

Claim 58 has been amended to clarify the term "at least one second."

Claim 61 has been amended to clarify that more than one additional agent may be present in the composition. Support for this amendment can be found, for example, in original claim 58.

Applicants submit that no new matter has been introduced as a result of the foregoing amendments.

Applicants submit herewith a Petition for Extension of Time (two months) and the requisite fee. Therefore, this Response is timely filed.

Double Patenting Rejection

Claims 1-18, 21-25, 52, 55, 57, 58 and 61 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 and 70-80 of U.S. Patent No. 5,958,436. Enclosed herewith is a terminal disclaimer in compliance with 37 C.F.R. §§3.73(b) and 1.321(b)-(c). Accordingly, Applicants respectfully request reconsideration and removal of this rejection.

Claim Rejections Under 35 U.S.C. §102(e)

Chow et al. (U.S. Patent No. 5,476,647)

Claims 1-5, 12, 21 and 24 stand rejected under 35 U.S.C. §102(e) as being anticipated by *Chow et al. (U.S. Patent No. 5,476,647, hereinafter "647")*. The Examiner states that '647 discloses a topical composition comprising water, acetic acid, and about 300mM calcium chloride having a pH of 6. Applicants respectfully disagree as follows.

'647 discloses therein a two-component composition designed solely for application to teeth (entire Specification and claims 1-30). The two components of the composition separately contain a soluble calcium source in the first component and a fluoride compound in the second component. The calcium-containing component further contains a calcium complexing agent. Both components contain buffers. The components of the composition are combined prior to application to teeth, resulting in the final formation of an insoluble calcium fluoride composition. The final composition is applied to teeth for the purpose of fluoridation.

The presently claimed composition relates to compositions for application to skin. Applicants have distinguished the mechanism of action of the claimed composition on skin from alternate mechanisms of action applicable to teeth (Specification page 13, line 21 through page 15, line 27). Applicants' composition is not useful for application to teeth.

Moreover, the presently claimed composition requires aqueous-soluble divalent calcium cation. The two-component composition disclosed in '647 results in the formation of calcium fluoride, which is insoluble in water. Applicants enclose herewith a copy from The Merck Index as evidence of such insolubility.

The Examiner has indicated that '647 discloses calcium chloride. Applicants respectfully disagree. Calcium chloride is present only in the first component of the two-component

composition and ceases to exist upon combination with the second component. Moreover, the Examiner has indicated that '647 discloses acetic acid. Acetic acid is present as a buffer only in the second component of the two-component composition. Thus, the Examiner's assertion that '647 discloses a composition comprising acetic acid and calcium chloride is incorrect, as they are never present in the same physical composition. Upon combination of the two components, insoluble calcium fluoride is formed.

As '647 fails to disclose one or more limitations of the presently claimed composition, Applicants respectfully request reconsideration and removal of the rejection.

Ito et al. (U.S. Patent No. 5,709,849)

Claims 1-3, 12, and 22 stand rejected under 35 U.S.C. §102(e) as being anticipated by Ito *et al.* (U.S. Patent No. 5,709,849, hereinafter "'849"). The Examiner states that '849 discloses a cosmetic composition comprising lactic acid and 0.5% calcium chloride. Applicants respectfully disagree as follows.

'849 discloses therein a composition designed for dermal moisture retention with reduced stickiness, said stickiness being attributed to the use of polyhydric alcohols and lecithens, and the reduction of stickiness being attributed to the incorporation of a bivalent metal salt of an organic acid (Summary of the Invention, col.2, lines 27-33, and claim 1).

The presently claimed composition requires an irritant ingredient capable of inducing skin irritation.

The Examiner has indicated that '849 discloses a cosmetic composition comprising lactic acid and 0.5% calcium chloride, as demonstrated in Table 1. Presumably, the Examiner believes that these two components represent a skin irritant ingredient and a calcium cation, as presently claimed. Applicants respectfully disagree. The '849 Specification plainly requires that the bivalent metal be present in the form of a salt of an organic acid. Clearly, the two ingredients shown in Table 1, calcium chloride and lactic acid, react such that the final composition comprises calcium lactate. The Examiner confirms this observation at page 4, paragraph 14 of the outstanding Office Action. As a result, the composition referenced by the Examiner fails to disclose each and every limitation of the claimed composition, by failing to disclose a skin irritant component.

Moreover, '849 does not even mention the concept of compositions that comprise an irritant ingredient capable of inducing skin irritation. In fact, none of the compositions disclosed in '849 contain ingredients in concentrations high enough to be capable of producing skin irritation. Accordingly, Applicants respectfully request reconsideration and removal of this rejection.

Claim Rejections Under 35 U.S.C. §103

Claims 1-18, 21-25, 52, 55, 57, 58 and 61 stand rejected under 35 U.S.C §103 as being unpatentable over Cormier *et al.* (U.S. Patent No. 5,624,415, hereinafter "'415") in view of Ito *et al.* ('849), Giddey *et al.* (U.S. Patent No. 5,053,219, hereinafter "'219"), Cook *et al.* (U.S. Patent No. 2,719,811, hereinafter "'811") and Henderson (U.S. Patent No. 5,296,476, hereinafter "'476").

Claims 6, 8, 9 and 52 have been canceled and therefore the rejection is moot in their respect.

Primary reference '415 was filed on April 24, 1995. The present application claims priority to U.S. Serial No. 08/860,959 (filed on June 23, 1997), which was a §371 national application based upon PCT/US95/16990 (filed on December 21, 1995), which claimed priority to U.S. Serial No. 08/362,101 (filed on December 21, 1994). Therefore, '415 does not qualify as prior art according to 35 U.S.C. §§102-103.

To the extent that secondary references have been cited, Applicants submit, as set forth below, that the secondary references fail to disclose or suggest the presently claimed compositions, either singly or in combination.

'849 fails to disclose or suggest the presently claimed compositions for reasons outlined in the previous section. Specifically, there is no disclosure or suggestion of compositions comprising irritant ingredients contained in an amount capable of inducing skin irritation, which is a limitation of the present claims. The Examiner has stated that '849 teaches the usefulness of organic salts of calcium in cosmetic products. Applicants submit, however, that the organic salts of calcium are employed in order to reduce the "stickiness" of moisture retention compositions.

There is simply no disclosure that relates the use of divalent calcium cations for topical reduction of skin irritations.

'219 discloses compositions comprising casein, wherein the casein is present, at least in part, as a colloidal and micellar solution of calcium phosphocaseinate (claim 1). The compositions necessarily comprise a surface active ingredient for the prevention of precipitation of calcium phosphocaseinate (column 3, lines 43-46). This clearly indicates that the calcium phosphocaseinate is poorly soluble in water, contrary to the presently claimed compositions, which require aqueous-soluble calcium cations. The '219 compositions are so designed in order to create stable compositions comprising milk proteins, which yield the appearance of natural milk-based cosmetic products (column 3, lines 24-31).

The Examiner has stated that '219 teaches a cosmetic composition having an organic acid (0.5-4% by weight) and calcium cation (0.1-1% by weight). Applicants respectfully disagree. While aqueous-soluble calcium salts may be used as starting materials, '219 clearly discloses their role as necessarily forming poorly soluble calcium phosphocaseinate in the resulting compositions (column 3, lines 62-63, and claim 1). Additionally, the presently claimed compositions do not require colloidal or micellar forms, as do those disclosed in '219. Moreover, '219 fails to teach or suggest skin irritant ingredients contained in an amount capable of producing skin irritation as a component of the disclosed compositions. There is simply no mention of skin irritants or the ability of divalent calcium cations to reduce their irritant effects.

'811 discloses the use of certain metals as capable of enhancing cellular respiration, stimulating metabolism, and offsetting certain types of toxicities (column 2, lines 18-25). The Examiner has stated that calcium metal with hydroxy acids are known to be beneficial to the skin. Applicants submit, however, that the benefits disclosed in '811 do not include anti-irritant properties. Nor do the compositions disclosed in '811 comprise irritant ingredients. Thus, '811 fails to teach or suggest the compositions that are presently claimed.

'476 discloses compositions comprising micronized calcium citrate in combination with salicylic acid for use in treating acne, fungal infections and for corn removal. Reduction of skin

irritation is not disclosed nor is it suggested. For reasons already of record in the parent application, '476 further fails to disclose or suggest the presently claimed compositions. For example, '476 relates to the precise combination of calcium citrate and salicylic acid. It is only the combination of those two specific ingredients that forms the basis of the '476 disclosure.

Calcium citrate is poorly soluble in water. '476 states in fact, that the calcium citrate is effective only in the form of a micronized powder (column 1, lines 62-64). Moreover, a saturated solution of calcium citrate has a concentration of only ~5.7mM, far below the anti-irritant level presently claimed.

Applicants further remind the Examiner that the ability of a composition to treat a particular condition, does not correlate to the composition's ability to reduce irritation caused by the condition. In fact, treatments can often lead to an increase in irritation throughout the duration of the therapy.

The secondary references all fail to disclose or suggest the presently claimed composition. While some of the references may be deficient in more than one respect, all of the cited references fail to disclose or suggest a composition comprising an irritant ingredient in an amount capable of inducing skin irritation in combination with an anti-irritant amount of a divalent calcium cation. Therefore, at least one of the presently claimed limitations is neither disclosed nor suggested by the secondary references, either alone or in combination.

The Examiner states that a person of ordinary skill in the art would have been motivated to employ calcium salts in a topical composition, and further, to employ calcium salts with organic acids in cosmetic compositions, wherein the acid may cause irritation. Applicants respectfully disagree with this assessment.

While calcium salts are commonly used in topical compositions, they previously were not known to be capable of reducing skin irritation. Therefore, it would not have been conceivable to design a cosmetic composition specifically incorporating ingredients known to cause skin irritation.

Moreover, metals such as calcium are generally included in cosmetic compositions as organic acid salts. Applicants submit that the acid salts of calcium disclosed in the prior art are

not disclosed as the "acids" relating to the irritant ingredients presently claimed. The Examiner has interchangeably discussed the organic acids used to form calcium salts with the free acids present as irritant ingredients. The Examiner has cited art disclosing compositions, for example, comprising calcium chloride and lactic acid. The Examiner has then attempted to use the two ingredients to satisfy three elements of the presently claimed composition. This is in error.

The Examiner readily admits that in such an example, the resulting compound would be calcium lactate, which would constitute only the anti-irritant and counterion components of the presently claimed composition. In such an example, an additional acid (or other irritant ingredient) would be required to fulfill all of the limitations recited in the present claims.

The Examiner has repeatedly asserted that organic acid salts of calcium are commonly used in cosmetic compositions. However, that fact does not render the instant claims obvious. In each of the cited examples, the presence of the organic acid merely forms a salt with the calcium ion, it does not function on its own as an irritant ingredient capable of inducing skin irritation.

The Examiner additionally has cited *In re Swinehart*, noting that the mere recitation of a newly discovered function or property, inherently possessed by a thing in the prior art, does not distinguish over the prior art. The Examiner concludes that the instant application is drawn to the ultimate utility set forth in the prior art, that is, the combination of organic acid and calcium. Applicants respectfully disagree.

The presently claimed composition is not directed to such a combination, although it may exist as a component thereof. The presently claimed composition is directed to the combination of an irritant ingredient and an anti-irritant ingredient, the specific combination of which is patentably distinct over the prior art. The irritant ingredient may or may not comprise an organic acid. The presence of the anti-irritant component, as a divalent calcium cation in its organic acid salt form, is not what is presently claimed in and of itself. Thus, each of the Examiner's examples of a calcium metal and an organic acid used to make its salt form, effectively satisfies only the anti-irritant and counterion components of the claimed composition. Accordingly, the body of the cited art fails to disclose or suggest the presently claimed composition, namely, the limitation of the irritant ingredient.

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Applicants submit that the present claims are novel and unobvious over the cited art. Accordingly, Applicants respectfully request reconsideration and removal of each of the outstanding rejections.

Should the Examiner consider a telephonic interview as being helpful in the examination of this application, an invitation is extended to contact the undersigned at the telephone number so indicated.

Enclosed is a \$260 check for the Petition for Extension of Time and Terminal Disclaimer fees. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Attachments: Terminal Disclaimer Under 37 C.F.R. §§3.73(b) and 1.321(b)
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